



MAY 31 2000

Mollie M. Yang
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Re: Patent Term Extension
Application for
U.S. Patent No. 5,565,473

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,565,473, which claims the human drug product SINGULAIR® and the method of use of SINGULAIR®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 430 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 430 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of March 3, 1999 (64 Fed. Reg. 10304). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,725 - 1,595) + 365 \\ &= 430 \text{ days}\end{aligned}$$

Since the regulatory review period began June 3, 1992, before the patent issued (October 15, 1996), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 3, 1992 to October 15, 1996 is 1,595 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,565,473
Granted	October 15, 1996
Original Expiration Date ¹ :	November 30, 2010
Applicant:	Michel L. Belley, et al.

¹Subject to the provisions of 35 U.S.C. § 41(b).

Owner of Record: Merck Frosst Canada & Co.²
Title: Unsaturated Hydroxyalkyquinoline Acids as Leukotriene Antagonists
Classification 514/313
Product Trade Name: SINGULAIR® (montelukast sodium)
Term Extended: 430 days
Expiration Date: February 3, 2012


Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: Crystal Plaza Four, Suite 3C23
2201 South Clark Place
Arlington, VA 22202

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


Karin L. Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852
RE: SINGULAIR®
FDA Docket No.: 98E-0843

²The change of name recorded at Reel 9578, Frame 0146 is noted.